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RESEARCH

A Tool to Assess Student Performance in a *Clostridium difficile* Infection Simulation Scenario

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Objective. To develop and validate an evaluation tool to assess student pharmacists' performance in a simulation scenario involving a patient with *Clostridium difficile* infection (CDI).
Methods. The authors used an expert panel review process to establish content validity of the tool. Four faculty members used the tool to evaluate student pharmacist groups during 2011 and tested a modified version of the tool in 2012. The authors analyzed the results for each year to determine internal consistency and inter-rater reliability.
Results. The 2011 tool demonstrated sound internal consistency, but several items had poor inter-rater agreement. The revised 2012 tool demonstrated acceptable internal consistency and good to excellent inter-rater agreement for all items except one.
Conclusions. The tool facilitated reliable assessment of student pharmacists' clinical decision-making during simulation performance involving a patient with CDI.
Keywords: assessment, simulation, evaluation tool, validation, clostridium difficile infection

INTRODUCTION

Assessment activities surrounding human patient simulation have focused on enhancing student pharmacists' exposure and confidence related to situations that occur in clinical practice. The majority of simulation activities incorporate formative feedback while providing student pharmacists the opportunity to practice skills and integrate various aspects of knowledge, communication, professionalism, and clinical application.[1] Educators commonly use survey data from learners to evaluate simulation-based activities.[2] Educators are also using pre- and post-knowledge testing more frequently.[3-6]

Effective assessment of clinical performance and critical thinking with simulation requires pharmacy educators to move beyond satisfaction and self-efficacy surveys and knowledge assessments to the development of reliable, valid tools to assess student performance during the simulation. This effort is becoming even more relevant as doctor of pharmacy (PharmD) curricula becomes more competency based. This transition is partly in response to the Accreditation Council for Pharmacy Education's (ACPE) recently approved Appendix D, a list of "must have" abilities indicating a student pharmacist's readiness to enter advanced pharmacy practice experiences (APPEs). The pre-APPE domains and abilities outlined in Appendix D require evidence of student pharmacist achievement of specific performance-based competencies prior to entering APPEs or clerkships.[7] Furthering the necessity for sound assessment practices to determine competency is that ACPE allows simulation-based activities to count for up to 20% (approximately 60 hours) of total introductory pharmacy practice experience.[8]

Basic components during the development of valid assessment tools include determination of content and construct validity and inter-rater reliability. Validity is a tool's accuracy in measuring what it was intended to measure. An accepted procedure is to use clinical experts to establish both content and construct validity. For content validity, the experts review the criteria in the tool and provide feedback regarding the appropriateness of the items and the key measurements required to evaluate each item. For construct validity, the experts assess how well an action represented the concept being evaluated.[2] Finally, the experts ensure that all important items are included on the tool and provide feedback regarding the relevance and importance of the items.

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Once the tool is developed, the next step is to establish its reliability. Reliability refers to the tool's ability to provide scores that are substantially free of measurement error. Of the many types of reliability that can be determined, inter-rater reliability is critical to establish when assessment of student learning will be conducted by many different graders from various clinical backgrounds. Inter-rater reliability is typically assessed when multiple raters independently evaluate the same performance using the same tool.

Faculty members at the Washington State University College of Pharmacy, initiated simulation-based activities within the PharmD curriculum during 2007. One of the initial simulation scenarios implemented was an infectious disease case related to *Clostridium difficile* infection (CDI). We selected this content area because of its importance to the healthcare system. *Clostridium difficile* is a widespread disease within healthcare systems and is the leading cause of nosocomial diarrhea.[9]

As part of the patient care team, pharmacists must/should understand the appropriate management of CDI. Pharmacists can play a critical role in identifying unwarranted agents that promote colonic stasis. Health care providers should avoid use of agents that reduce gastric motility in patients with CDI because of the potential risk of severe complications such as toxic megacolon.[9] Pharmacists can assist with treatment optimization, thereby reducing the infectious spread of CDI to other patients. A multidisciplinary CDI reduction team led by a pharmacist was associated with a reduction in the rate of CDI within the Huntsville Hospital System.[10] As healthcare professionals with direct patient contact, pharmacy personnel must actively use proper infection control procedures to prevent the nosocomial transmission of this pathogen.

We developed a simulation evaluation tool, including proper infection control procedures and therapy optimization, to address the role of the pharmacist in appropriate treatment of CDI. Despite the expansion of simulation-based teaching methodologies, few studies have been published in the pharmacy literature regarding the validation of simulation assessment tools. Thus, the purpose of this study was to validate the evaluation tool with a specific focus on establishing content validity and inter-rater reliability.

METHODS

The WSU Institutional Review Board granted "exempt" status to this study as normal education practice conducted in an established educational setting. We completed the tool validation process over a 2-year period, beginning in fall 2010, with content validation, tool creation, and preliminary testing in spring 2011, followed by tool revision and further testing in spring 2012. The tool developers identified the following 6 content domains which they believed were important to include on an assessment tool: isolation precautions, assessment of home medications and current medication orders, appropriate monitoring parameters, evaluation of diagnostic results, accurate treatment of CDI, and appropriate supportive care. We used a deductive process to develop individual items for each content domain. A 6-person clinical expert panel that included 3 infectious diseases pharmacists, 1 infectious diseases physician, 1 internal medicine pharmacist, and 1 postgraduate year 1 (PGY1) pharmacy resident reviewed the 6 content domains and their associated items.

The experts evaluated the items in the 6 content domains, rating each as critically important, important, not very important, or not important at all. Additionally, they suggested revisions to existing items and identified missing items. The expert reviewers also ranked items of pharmacist-specific patient care in order of importance relative to each other. Based on the results of the expert review, we developed the first 18-item draft of the checklist style tool, including the assignment of point distribution on the tool.

We used the initial draft tool to evaluate the performance of 24 student pharmacist groups during the spring 2011 simulation. Each simulation session was video recorded and saved in digital format to a secure university server. Four raters independently assessed student performance from the video recordings. We analyzed 4 independent raters' summed scores across the items to determine the internal consistency and reliability of the entire evaluation tool, as well as for individual items. The tool validation team reviewed the results from the 2011 spring semester analysis and revised the tool. The revised tool (Appendix 1) with 19 check-list items, was then used to evaluate the performance of 31 student groups during 2012 spring semester. The video-recordings and the independent video-recording rater processes were consistent with the methods used in 2011. Team members again reviewed the overall tool and each item and compared it to the previous tool to determine if its performance had improved. Special focus was given to the items regarding accurate therapy to determine if those had changed from the previous tool.

The course faculty members created an education module to introduce second-year student pharmacists to a hospitalized patient with CDI. The educational module was delivered in an applied patient care laboratory which included a 1-hour tutorial followed by a 2-hour laboratory component. The student pharmacists were required to read *Clinical Practice Guidelines for Clostridium difficile*

Infections in Adults prior to tutorial and laboratory. In addition, prior to the laboratory session, course faculty members provided the students with the patient's admission note from the physician. [11] Learning objectives for the CDI simulation included that after completion of the module, the student would be able to do the following: (1) list risk factors for CDI, (2) recommend appropriate CDI therapy, (3) indicate measures used for supportive care and identify medications that should be avoided or used with caution, and (4) establish appropriate monitoring parameters to evaluate the therapeutic improvement or treatment failure of a patient. The tutorial included a brief orientation to the CDI case, a review of the patient chart, and a review of a simulation confidentiality statement.

Student pharmacists were divided into teams of 3 to 4 students. The simulation began with a brief interaction with the facilitator who provided a short, scripted introduction describing the simulated patient case setting. The student pharmacists began the simulation by conducting a chart review at a mock nursing station. They then entered the patient room and performed a patient interview. Immediately following the patient interview, the facilitator entered the patient room where 1 of the student pharmacists on the team initiated a short, informal patient case presentation. The facilitator encouraged other team members to participate by adding relevant information to the presentation. After the students completed the simulation, the facilitator conducted a short debriefing and discussion with the student pharmacists in a separate conference room. During the debriefing, the facilitator evaluated the student pharmacists' performance and provided formative feedback.

The simulations were conducted over 2 days. The same basic patient case was used for all simulations but the patient medical record and outcome were changed between days to limit the impact of discussion between student pharmacists who had completed the simulation and those who had not. In one case the patient's condition deteriorated and he did not respond to the initial therapy of metronidazole. For the second case, the patient improved with the initial therapy. Each scenario provided opportunity for the student pharmacists to obtain pertinent information from the patient, practice appropriate infection control procedures, modify drug therapy regarding duration and dosing, and discontinue contraindicated therapy.

The statistical analyses were consistent for both the 2011 and 2012 tool versions. Summed scores across all the items from 4 independent raters were analyzed using Cronbach alpha to determine internal consistency reliability of the entire evaluation tool. We assumed the overall instrument to be internally consistent at a Cronbach alpha value >0.80.[12,13]

The summed scores were derived from dichotomous ratings per item by each rater (1 = aspect observed, 0 = aspect not observed). Cronbach alpha across all raters for all groups was calculated as well as for groups with the "deteriorating" patient and those with the "improving" patient. Observed percent agreement values amongst the 4 raters per item across all scenarios were calculated. Gwet's first-order agreement coefficient, AC_1, was used to estimate chance-adjusted agreement among the 4 raters for each item on the evaluation.[14,15] AC_1 uses a chance-agreement probability that is calibrated to the propensity of random ratings estimated from observed ratings. Unlike other measures of chance-adjusted agreement, such as Cohen's Kappa, AC_1 is not distorted by high (or low) prevalence of the trait being rated; thus, it represents an unbiased estimate of 'true' inter-rater agreement.[16,17] Confidence intervals for AC_1 were derived with unconditional variance estimates in order to characterize precision of the agreement coefficients to the general population of raters. Items with AC_1 values below 0.60 were scrutinized for revision. All calculations were performed with SAS software.[18]

RESULTS

The experts rated accurate treatment of CDI and assessment of home medications and current medications as critically important. They rated all other domains as important. The experts ranked the most relevant pharmacist-specific patient-care item as accurate treatment of CDI followed by, in order of decreasing importance, evaluation of home and acute care medication orders, patient monitoring, evaluation of diagnostic tools, isolation precautions, allergy status, and estimation of renal function.

Results from 2011 Tool

Cronbach alpha for all groups across both scenarios (n = 23 groups) was 0.887. Cronbach alpha for the scenario in which the patient was decompensating (n = 14 groups) was 0.932; and for the scenario in which the patient was improving (n = 9 groups) was 0.779. In general the magnitude of Cronbach alpha indicated sound internal consistency across scenarios and for scenarios with a patient who was deteriorating or improving.[13]

Gwet's AC_1 inter-rater agreement coefficients plus/minus the standard error for each item across the overall scenario, as well as for the decompensating and the improving patient, ranged from 0.97 ± 0.3 (high agreement) for "exhibited professional behavior" to 0.29 ± 0.29 (low agreement) for "general wellness" between the 4 raters. Table 1 reflects the items identified for revision on the 2012 version of the tool. The table identifies the disposition of those items. The item, "followed simulation guidelines,"

Table 1. Spring 2011 Tool – Analysis for Items with AC_1 less than 0.60[a]

Checklist Items	Inter-rater Agreement Coefficient (SE)[a]			Revisions of Checklist Items for 2012 Tool
	Both Scenarios	Decompensating Patient Scenario	Improving Patient Scenario	
Followed simulation guidelines (Item 1)	[b]	[b]	[b]	Eliminated item: not essential for determining student competency
Assessed Current Medication Orders (Item 6)	0.57 (0.26)	0.52 (0.36)	0.59 (0.25)	Revised item: Split into 2 separate items - review of MAR for current hospital meds and patient interview for verification of home meds.
General Wellness (Item 13)	0.35 (0.22)	0.29 (0.29)	0.34 (0.30)	Eliminated item: poorly worded & not essential for determining student competency
Treatment – Recommend appropriate therapy based on Severity (Item 17)	0.71 (0.14)	0.52 (0.22)	0.92 (0.10)	Revised these 2 items: Developed 4 distinct items to address each aspect of appropriate therapy – drug choice, correct dose, correct route, correct duration
Treatment – State Specific Drug, Route and Duration (Item 18)	0.49 (0.28)	0.55 (0.25)	0.42 (0.35)	

[a] Reported as Gwet's first-order agreement coefficients, AC1, to estimate chance adjusted agreement amongst the 4 raters for each item with standard errors reported in parentheses.
[b] Chance agreement not calculable under conditions of 100% agreement.

was removed from the tool because of a perfect inter-rater reliability and a decision from the tool development team that the item was nonessential. The item, "general wellness," was included on the tool to determine if student pharmacists evaluated the patient's total well-being. The item was removed from the tool because of poor inter-rater reliability and recognition that it was poorly worded, leading to multiple interpretations among raters.

Three items were revised to improve clarity in the evaluation of appropriate drug therapy. The item "assessed current medication orders" was separated into 2 items to evaluate if the students were reviewing both the medication administration record (MAR) and evaluating home medications. Review of the MAR was important to ascertain if students were evaluating current inpatient drug therapy, and the relevance of home medications was to identify potential offending agents. The items "recommend appropriate therapy based on severity" and "treatment" were reconfigured into 4 distinct items focusing on the students' abilities to make a patient-specific drug therapy recommendation for the treatment of *C. difficile* disease, including specific drug, correct dose, correct route, and correct duration.

Results from 2012 Tool

Cronbach alpha across all raters for all groups (n = 31 groups) was 0.82. Cronbach alpha for the scenario in which the patient was decompensating (n = 17 groups) increased to 0.86 and for the 14 groups who experienced an improving patient (n = 14 groups), decreased to 0.75. In general, the magnitude of Cronbach alpha indicated that the tool had acceptable internal consistency, as a whole, and for scenarios in which a patient was deteriorating or improving.[13]

The magnitude of chance-adjusted agreement among raters per item was good to excellent ($> 0.69 \pm 0.09$) with the exception of item 18 which revealed only fair chance-adjusted agreement for both scenarios (0.40 ± 0.10).[19] Table 2 highlights the performance of the *revised items* on the 2012 tool.

DISCUSSION

We conducted the study to determine the validity and reliability of an evaluation tool designed for the purpose of assessing student pharmacists' skills during a simulation scenario involving a patient with CDI. The final 2012 version of the simulation assessment tool was sound with respect to content validity, demonstrated acceptable levels of inter-rater reliability per item, and exhibited sound internal consistency, whether the scenario involved a patient who was improving or deteriorating.

Potential weaknesses of the study were identified by the team. Prior to using the 2011 and 2012 CDI evaluation tools, graders did not participate in norming sessions. By discussing how the tool would be used, the raters may have been able to identify a clear vision of the intent for

Table 2. Spring 2012 Tool – Analysis of Revised Items[a]

Checklist Items for 2012 Tool	Inter-rater Agreement Coefficient (SE)[a]			Comments
	Both Scenarios	Decompensating Patient Scenario	Improving Patient Scenario	
MAR Review (Item 9)	0.93 (0.04)	0.92 (0.06)	0.95 (0.05)	Revised from 2011 Item 6 (Assessed Current Medication Orders)
Home Medications Assessed (Item 11)	0.83 (0.06)	0.85 (0.07)	0.90 (0.11)	Revised from 2011 Item 6 (Assessed Current Medication Orders)
State Specific Drug for treatment of *C. difficile* disease (Item 16)	0.85 (0.06)	0.85 (0.08)	0.84 (0.10)	Revised from 2011 Item 17 (Recommend appropriate therapy based on Severity) and Item 18 Treatment (State Specific Drug, Route and Duration)
Correct Dose for *C. difficile* disease (Item 17)	0.72 (0.09)	0.67 (0.13)	0.78 (0.12)	
Correct Route for *C. difficile* disease (Item 18)	0.40 (0.10)	0.50 (0.15)	0.29 (0.13)	
Correct Duration for *C. difficile* disease (Item 19)	0.69 (0.09)	0.79 (0.10)	0.57 (0.17)	

[a] Reported as Gwet's first-order agreement coefficients, AC1, to estimate chance adjusted agreement amongst the 4 raters for each item with standard errors reported in parentheses.

each item, potentially increasing inter-rater reliability. Evidence of this was discovered with the "correct route" item which demonstrated a low AC_1 score. Student pharmacists tended to leave the route out, particularly if they were modifying the drug dose but retaining the original route of administration. The route of administration was often "implied." Second, the evaluators then inconsistently gave credit (or not) for route of administration used. Some raters indicated that if the students did not explicitly state the route used, they did not give credit for it, while others gave credit for the students when they implied which route was used. This emphasizes the importance of including norming sessions during tool validation processes.

During 2011, the audio was not recorded while the students were reviewing the patient charts, and the video capture of the patient charts was sometimes of a low quality. Video raters reported difficulty seeing what portion of the chart was being reviewed and did not have the ability to listen to discussions between student pharmacists while evaluating the patient chart. During 2012, both audio and video of the chart review were available for the raters to review during the evaluation.

Traditional assessment of student learning relies heavily on the ability of students to demonstrate achievement of knowledge-based content through the use of written examinations. However, performance on a written examination does not ensure competency in the provision of patient-specific care. An example relevant to this scenario is that student pharmacists may pass a written assessment illustrating they understand the importance of following isolation precautions when encountering infectious material. However, whether they can incorporate this knowledge into practice is unknown. Performance-based assessment allows evaluation of this competency. Assessment of performance "requires students to display their learning. . .actively practice their skills and synthesize their knowledge."[20] In the area of advanced cardiac life support (ACLS), checklists can be used to make valid judgments of minimum competencies.[21,22] Also, reliable scores can be obtained through the use of an ACLS checklist during a high stakes performance assessment, called a Megacode, used during ACLS certification.[23] To this end, the need for valid, reliable assessment tools to evaluate skills-based performance of student pharmacists during simulation cannot be overstated, particularly as pharmacy education programs are called to provide evidence of competency/mastery of pre-APPE domains. Future studies based on these results are needed to target the best approach for using evaluation tools to set standards of proficiency in pharmacy practice.

Additionally, there is a need to continue to define and implement authentic assessments as a best practice in pharmacy education. While there is not a single definition, authentic assessment is defined by Frey and colleagues as an assessment that is a "mirroring of real-world tasks or expectations."[24] For healthcare workers our "real-world" is the provision of patient care. Developing reliable assessment tools for simulated patient cases may be the first step to authentic assessment. Reliable assessment tools must have a defensible cut point, consistent between raters, and include content needed to treat a patient.[25]

CONCLUSION

Using the evaluation tool described for assessing a *Clostridium difficile* infection simulation scenario, student pharmacists were graded consistently among multiple graders. Additionally student pharmacists were evaluated on CDI content deemed important and relevant by experts in the field. Establishing a valid, reliable assessment tool to evaluate student performance during a simulation scenario lays the foundation for simulation to be used more commonly as summative evaluation to ensure that student pharmacists meet the pre-APPE core domains and abilities.

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Appendix 1. 2012 CDI Evaluation Tool

Evaluator: _____ **Student Group # :** _____

Elements to assess	KEY		De-briefing Guidance/Notes
Simulation etiquette, preparedness, professionalism, and respect **_____/1.5 pts**	Exhibited ***professional behavior*** during simulation and debriefing • introduces self • White coat/Name Badge • Treats manikin as a patient **YES (1.5 pt)** **NO (0 pt)**		- Each group can be graded as a whole - Note below those students who are deficient in any area
Personal Protection **_____/2 pts**	Practiced Isolation Precautions • Gloves • Gown Performed hand hygiene prior to leaving patient room	**YES (1 pt)** **NO (0 pt)** **YES (1 pt)** **NO (0 pt)**	Proper isolation precautions for c. diff includes: gloving & gowning (covers all articles of clothing; not visibly falling off) Proper hand hygiene for c. diff: warm/soapy water for 30 seconds will kill the spores; hand sanitizer may not be substituted.
Consulted Patient Chart **_____/3 pts (0.5 pts each)**	Laboratory data Graphic Pain flow sheet *C. difficile* diagnostic information Current provider medication orders MAR	**YES (0.5 pt)** **NO (0 pt)** **YES (0.5 pt)** **NO (0 pt)** **YES (0.5 pt)** **NO (0 pt)** **YES (0.5 pt)** **NO (0 pt)** **YES (0.5 pt)** **NO (0 pt)**	• Vitals: temperature, pt weight, HR BP Temp conversions: (F-32) X 5/9 = C (C X 9/5) + 32 = F • Ins and Outs (# of stools) • Pain control • Lab data: WBC, Scr, electrolytes Evaluation diagnostic tools/ results to determine appropriate need for treatment • Stool culture • Enzyme immunoassay (EIA) for Toxin A and B • Glutamate dehydrogenase (GDH) • Polymerase Chain Reaction **Current meds (in hospital):** • Determine amount of prn drug usage (i.e. morphine sulfate, Imodium®) • Establish current treatment for Clostridium *difficile* disease

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Elements to assess	KEY		De-briefing Guidance/Notes
Interviewed Patient **_____/2.0 pts**	Verify Allergy status	**YES (0.5 pt)** **NO (0 pt)**	**Home meds:** • atropine/diphenoxylate (Lomotil®): 0.025mg/2.5mg 1-2 tablet po QID prn • dicyclomine (Bentyl®): 10mg po daily (omitted- student pharmacist to clarify) • establish previous exposure to antibiotics for tooth infection
	Verify home medications	**YES (0.5 pt)** **NO (0 pt)**	**Characteristics of Stools:** • Frequency: # of BMs • Consistency: watery vs. formed
Students need to ask Mr. Able about other home medications besides the Chantix® (which is listed in H&P)	Characteristics of stools	**YES (0.5 pt; 0.25 pt for frequency & consistency)** **NO (0 pt)**	**Pain assessment:** • Pain scale • 3 or more OLDCART questions
	Pain (pain scale, OLDCART questions)	**YES (0.25 pt for pain scale; 0.25 pt for 3 or more OLDCART questions)** **NO (0 pt)**	
Accurate treatment of *C. difficile* based on published guidelines and severity of disease **_____/4.5 pts** Avoid medications that will slow gut motility or cause constipation. Excretion of toxin may be preventing which could lead to accumulation of the toxin in the bowel (ultimately toxic megacolon and/or bowel obstruction)	Discontinue anti-diarrheals.	**YES (1 pt)** **NO (0 pt)**	Must verbalize discontinuing anti-diarrheal/Imodium®. May consider changing morphine sulfate to non-opiate therapy, but not required for grading.
	Differentiate severity of disease • Mild, moderate, severe • Responding vs. non-responding • Improving vs. not improving	**YES (1 pt)** **NO (0 pt)**	**Not improving: Severe** • # of stools per day (range 10-14) has not significantly decreased consistency not changed/improved. • Temp range: 36.7 – 38.5° C (still febrile at times) • WBC: 42, 40, 39 and Bands: 70, 40, 50% (no appreciable improvement) • Hydration status: K+ has increased to 4.9 • Pain scale/discomfort report – no improvement **Improving: Mild to Moderate** • # of stools per day (range 4-5) decreased; consistency improved. • afebrile: Tmax = 37° C (not febrile) • WBC: 14, 13, 11 and Bands: 70, 40, 25% (trending improvement) • Hydration status: K+ has increased to 4.9 • Pain scale/discomfort report – improved

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Elements to assess	KEY		De-briefing Guidance/Notes
	Recommend appropriate therapy based on severity of disease.		**Therapy:**
	☐ State specific drug ☐ metronidazole ☐ vancomycin	**YES (1 pt)** **NO (0 pt)**	**Not improving:** At this point it would be appropriate to change antibiotic therapy to vancomycin 125mg po four times a day for 10-14 days.
	☐ correct dose	**YES (0.5 pt)** **NO (0 pt)**	**Improving:** Metronidazole is effective (noted improvement) so should consider readiness for discharge. Emphasize alcohol avoidance.
	☐ correct route	**YES (0.5 pt)** **NO (0 pt)**	Other (supportive care): • Suggest dc of morphine (or change to prn). Suggest alternative for pain control - NSAIDS (after evaluating renal function). • Consider changing IV to decrease total daily potassium. (K+ has increased to 4.9 while JA has been on a D5-1/2NS w/ K infusion)
	☐ correct duration	**YES (0.5 pt)** **NO (0 pt)**	Not improving: Note lack of treatment for fever control. **Consider adding acetaminophen 500mg po Q 4-6 prn fever/pain.**
TOTAL Possible Points:	**_____/13 points**		